

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-03-8003]

DDM

Display Date	<i>7-6-05</i>
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Officer	<i>A. Corbin</i>

Memorandum of Understanding Between the U.S. Food and Drug
Administration and Howard University, Washington, DC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the U.S. Food and Drug Administration and Howard University, Washington, DC. The purpose is to implement an integrated system of shared interest in scientific progress through an exchange of scientific capital in the diverse fields of science that directly and indirectly affect human and animal health and medicine.

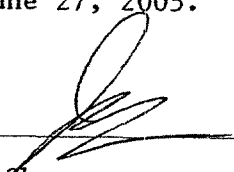
DATES: The agreement became effective May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Judy Blumenthal, Office of Science, Food and Drug Administration, 200 Independence Ave. SW., Washington, DC 20201, 202-260-0677.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: 6/27/05

June 27, 2005.

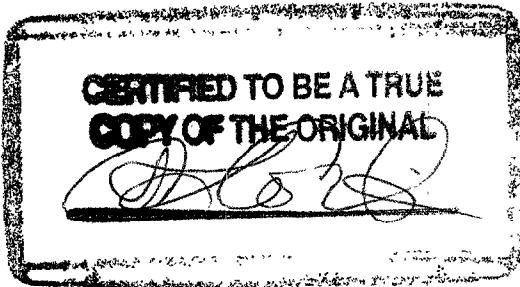


Jeffrey Shuren,
Assistant Commissioner for Policy.

[INSERT MOU]

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S



MEMORANDUM OF UNDERSTANDING

between

THE UNITED STATES FOOD AND DRUG ADMINISTRATION

and

HOWARD UNIVERSITY

WASHINGTON, D.C.

The United States Food and Drug Administration (FDA) and Howard University (Howard) have a shared interest in scientific progress through an exchange of scientific capital in the diverse fields of science that directly and indirectly affect human and animal health and medicine. Both institutions also endorse scientific training for academicians and students to foster a well-grounded foundation in interdisciplinary science on which scientific learning will grow.

This Memorandum of Understanding (MOU) establishes terms of collaboration between FDA and Howard to support these shared interests that can proceed through a variety of programs such as sabbaticals, postdoctoral fellowships, and student internships.

I. Food and Drug Administration

FDA will provide Howard with the following resources and/or opportunities in relation to sabbaticals, postdoctoral fellowships, student internships, and/or other research or training programs that involve joint Howard and FDA research interests and scientific objectives:

- Laboratory and/or office space as needed.

Use, sharing, and loan of equipment will be considered as part of future and specific Cooperative Research and Development Agreements (CRADAs), Material Transfer Agreements (MTAs) or other appropriate agreements that may be developed between Howard University and FDA. Specifically, equipment requests will be handled in accordance with the Stevenson-Wydler Technology Innovation Act of 1980, the Federal Technology Transfer Act of 1986, the Technology Transfer Commercialization Act of 1995, and other federal law and Agency policy.

- Openness and proactive efforts in establishing collaborative scientific, research and training initiatives
- When opportunity allows, FDA will provide strong positive initiatives and proactive efforts in establishing collaborative scientific, research, and training initiatives with Howard faculty, students, and staff.
- When opportunity allows, FDA will share research methodologies in accordance with federal law and Agency policy. All methodologies will be redacted to protect proprietary and confidential information.
- Based on available resources, willingness to participate in graduate courses and seminars at Howard.
- Continuing and frequent communication with faculty and staff.

- FDA will invite Howard University to participate as an active participant or presenter in the annual FDA Science Forum. Other official forums will be handled in accordance with HHS's Office of Special Counsel for Ethics Co-Sponsorship Guide dated August 8, 2002.

The word "Visiting Scientist" for Howard University faculty will be those individuals who are on sabbaticals at FDA. University faculty will have opportunities to apply for sabbaticals with the Agency with terms of the sabbatical, and its funding, to be negotiated between the individual and the Agency. Howard faculty will be allowed to apply for salary support, where appropriate, through a variety of funding mechanisms. Request for salary support must coincide with the current federal fiscal year. Howard faculty may also apply for positions through the Intramural Research Training Act (IRTA) Program and the FDA Service Fellowship Program, and may submit a request to be an Expert and Consultant, or work as a Volunteer. Howard faculty will also be given opportunities to attend a variety of didactic courses.

- Promulgation and communication of this collaborative effort through web pages, informal conversations with colleagues, faculty and students.

In addition to the above, FDA will provide Howard personnel the following:

In the Sabbatical Program:

- Opportunities to apply for a sabbatical with the agency with terms of the sabbatical to be negotiated between the individual and the agency.

- Opportunity to attend a variety of didactic courses.

In the FDA Service Fellowship Program:

- Opportunity to compete for appointments.

Howard University graduate and professional students will have opportunities to participate in FDA student programs, when appropriate, and based on availability of funds. An example would be funding provided by the National Science Foundation through the Washington Baltimore Hampton Roads Alliance for Minority Participation (WBHR-LSAMP). Howard University will review and pre-select the eligible student, and FDA will approve the student subject to FDA criteria for its student programs. With concurrence of both parties on a research project, FDA, as appropriate, will offer office support, laboratory support, and supplies. Consistent with Howard and FDA rules and regulations, and negotiated on a case-by-case basis, FDA mentors can, where appropriate, serve on thesis committees, attend examination and committee meetings, and participate in other aspects of the student's educational program at Howard. As appropriate, encouragement and welcome to students wishing to rotate through FDA laboratories and review divisions will be of the highest priority, as well as an opportunity for these and others to obtain short-term training in related areas. In addition, Howard University undergraduate students are welcome to apply to the Center for Veterinary Medicine (CVM) Summer Intern Program (http://www.fda.gov/cvm/intern/student_intern.htm#Program).

In the Graduate Student Internship Program:

Howard University will review and pre-select the eligible student, and FDA will approve the student subject to FDA criteria for its student programs.

- With concurrence of both parties on a research project, FDA, as appropriate, will offer office support, laboratory support, and supplies.
- Consistent with Howard and FDA rules and regulations, and negotiated on a case-by-case basis, FDA mentors can, where appropriate, serve on thesis committees, attend examination and committee meetings, and participate in other aspects of the student's educational program at Howard.
- Howard University graduate and professional students will have opportunities to participate in FDA student programs, when appropriate, and based on availability of funds. An example would be funding provided by the National Science Foundation through the Washington Baltimore Hampton Roads Alliance for Minority Participation (WBHR-LSAMP). Howard University will review and pre-select the eligible student, and FDA will approve the student subject to FDA criteria for its student programs. With concurrence of both parties on a research project, FDA, as appropriate, will offer office support, laboratory support, and supplies. Consistent with Howard and FDA rules and regulations, and negotiated on a case-by-case basis, FDA mentors can, where appropriate, serve on thesis committees, attend examination and committee meetings, and participate in other aspects of the student's educational program at Howard. As appropriate, encouragement and welcome to students wishing to rotate through FDA laboratories and review divisions will be of the highest priority, as well as an

opportunity for these and others to obtain short-term training in related areas. In addition, Howard University undergraduate students are welcome to apply to the Center for Veterinary Medicine (CVM) Summer Intern Program (http://www.fda.gov/cvm/intern/student_intern.htm#Program).

General Appointments:

- Opportunity to submit resumes to apply for Special Government Employee (SGE) appointments.

II. Howard will provide the FDA with the following resources and/or opportunities in relation to sabbaticals, postdoctoral fellowships, student internships, and/or other research or training programs that involve joint Howard and FDA research interests and scientific objectives:

- Laboratory and/or office space as needed.
- Openness and proactive efforts in establishing collaborative research efforts with FDA scientists and staff.
- Continuing and frequent communication with FDA scientists and staff.
- Openness and welcome to FDA scientists and staff wishing to visit relevant Howard programs and laboratories.
- Promulgation and communication of this collaborative effort through web pages, informal conversations with colleagues, faculty and students.

In addition to above, Howard will provide FDA personnel the following:

In a Sabbatical Program at Howard:

- Opportunities to apply for a sabbatical with Howard. Terms of the sabbatical will be negotiated between the individual and the appropriate University unit.
- Opportunity to attend and/or participate in a variety of courses at the graduate level.

For Howard Graduate Students:

- Opportunity to receive dissertation research credits from the Graduate School, when available and appropriate, for Howard students engaged in dissertation research while participating in an internship at an FDA Center.
- Encouragement of graduate students to rotate through, and/or have short-term research opportunities in FDA laboratories.
- Adjunct faculty appointments in relevant Howard programs or departments, based on available resources and consistent with standard Howard policies, for those FDA staff members working with Howard students, and/or assisting in teaching at Howard.

III. Coverances

Howard individuals participating in the MOU will be United States Citizens or Permanent Residents. Regarding the latter, all federal restrictions will be adhered to.

Patent, license, and other legal instruments will be prepared in accordance with federal law and Howard policy, and written notice referencing the policies will be provided to the individual prior to entering on duty with FDA.

Howard and FDA may decide to enter into a Cooperative Research and Development Agreement (CRADA) at a future time to conduct collaborative research. The terms of such a CRADA will address Intellectual Property rights.

This MOU forms the basis for the initial relations between FDA and Howard for sabbaticals, research, and scientific education. However, as this collaborative effort progresses, it is expected that new and wider areas of mutual interest will evolve and be included in expansions of this document. Therefore, this MOU will be reviewed no later than five years after signature.

Howard and FDA are entering into this MOU in anticipation of a collaboration that will be memorialized in an agreement that has yet to be executed.

IV. Finances and Resources

Howard and FDA agree that this MOU does not commit either to make specific levels of financial or personnel support or to provide specific laboratory or office space for the programs and that the provision of such support will be based on available resources and provided in accordance with the rules, regulations and laws under which FDA operates and the policies of Howard.

V. Contact

The individual to whom all inquiries to FDA should be addressed is:

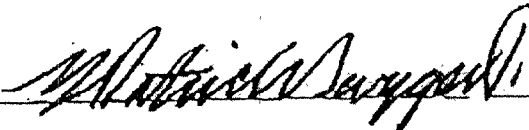
Judy Blumenthal, Ph.D.
Jblument@oc.fda.gov

The individual to whom all inquiries to Howard should be addressed is:

Pedro J. Lecca, Ph.D., R.Ph., LMSW
Dean and Professor
College of Pharmacy, Nursing and Allied Health Sciences
plecca@howard.edu

AGREED TO:

HOWARD UNIVERSITY

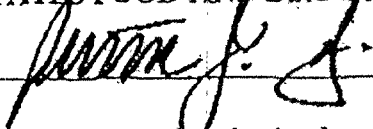
BY:  4/29/03

Signature of authorized representative

Date

H. Patrick Swygert, Esq., J.D.
President
Howard University

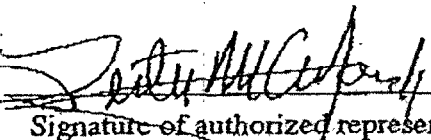
UNITED STATES FOOD AND DRUG ADMINISTRATION

BY:  4/29/03

Signature of authorized representative

Date

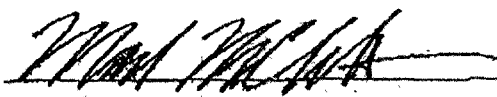
Peter J. Pitts
Associate Commissioner
Office of External Relations
Food and Drug Administration

BY:  May 29, 2003

Signature of authorized representative

Date

Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner of Food and Drugs

BY:  Apr 29, 2003

Signature of authorized representative

Date

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs